CONSENT FOR RESEARCH USE OF PATIENT TISSUE AND INFORMATION

Title of Research: Protocol for Obtaining Solid Tissues, Fluids, and Information for Research for the UAB Tissue Collection and Tumor Banking Facility Including the Breast, Ovarian and Pancreatic SPORES, the Cooperative Human Tissue Network, the Cancer Center Tissue Core Facility, and the Genitourinary Research Center.
Investigator: William E. Grizzle, M.D., Ph.D.
Sponsor: National Cancer Institute

Explanation of Procedures: A key mission of The University of Alabama at Birmingham (UAB) is research about diseases. We would like your permission to use samples of your tissue (e.g. operative specimens, blood, urine, and saliva if available) and information about you in this research designed to improve care of various diseases. As you are a patient of UAB, your privacy and the confidentiality of your information are very important to us and will be protected.

You are being asked to grant permission for your tissues and fluids to be distributed by the UAB Tissue Collection and Tumor Banking Facility to researchers within the UAB community and throughout the United States and Canada as they search for cures for cancer and other diseases. These researchers need access to normal, diseased, and malignant tissues for their studies. In some cases, you will be asked to provide for research, samples of blood (20 milliliters or 5 teaspoons), urine and/or saliva. **Otherwise, only excess tissues and fluids, which are not needed for diagnosis, and otherwise would be discarded, will be provided for research**. Any research specimens obtained will come from procedures already scheduled, and **NO** surgical procedure will be performed on you for the specific purpose of obtaining specimens for research unless you consent separately. Some of these excess tissues and fluids may be stored for future research studies.

You are also being asked for permission to obtain from your medical records information about your history and treatment that will make your tissue samples even more useful to the research community.

Risks and Discomforts: There may be a slight pain and discomfort associated with obtaining the samples of blood. Bruises at the site of blood drawing may occur and very rarely, local infections. Otherwise, all specimens obtained for research will come from excess tissue obtained from routinely scheduled procedures. You will experience minimal risk by granting consent for this protocol. The main potential risk to you is accidental release of your medical information. To protect your information, all information is maintained in secure facilities and all samples used for research have coded identifiers and are kept in secure and confidential tissue banks.

Benefits: Participating in the research effort can be your contribution to UAB's work to find cures for diseases and to improve the care of patients with various diseases. While the research that may be done with your tissue and information is not designed to help you specifically, it may help in the future treatment of conditions like yours and may aid in your future medical care and that of your family.

Alternatives: Your alternative is to not participate in the study. This will not affect your care.

Specific Consent for Other Research: You may be asked at a later time to participate in other research that involves more than use of tissue and information. At that time you will be given specific information about that trial or study and asked to sign another specific consent form before participating in the clinical trial or study. You will be asked for specific consent for any research that involves more than a minimal risk.

Confidentiality: Information obtained concerning your condition/disease and your identity will be kept confidential to the extent permitted by law. However, your doctor, representatives of the UAB Tissue Collection and Tumor Banking Facility, and UAB's Institutional Review Board (IRB) will be able to inspect your medical records and have access to confidential information that identifies you by name. Neither your name nor any identifying information will be revealed to the researchers who receive your samples. You agree that the scientific measurements and the extent of your condition/disease and its outcome may be published for scientific purposes provided your identity is not revealed. If you receive services in University Hospital as part of this trial, this informed consent document will be placed in and made part of your permanent medical record at this facility.

Withdrawal without Prejudice: You are free not to participate in this study and the decision not to participate will not affect your medical care. You are free to withdraw your participation at any time without prejudice against future care you may receive at this institution.

Cost for Participation: There will be no cost to you for participating in this study.

Payment for Participation: There will be no payment for participating in this study.

Injury Compensation Clause: UAB has made no provision for monetary compensation in the event of injury resulting from the research and in the event of such injury, treatment is provided, but is not provided free of charge.

Questions: If you have any questions about the research or research-related injuries, Dr. William E. Grizzle, or Dr. Grizzle's assistant, Ms. Katherine Sexton, will be glad to answer them. Dr. Grizzle and Ms. Sexton may be reached at 205-934-6071. If you have questions about your rights as a research participant, Ms. Sheila Moore, Director of the Office of the Institutional Review Board for Human Use (IRB) will answer them. Ms. Moore can be reached at (205) 934-3789 or 1-800-822-8816, press the option for an operator/attendant and ask for extension 4-3789 between the hours of 8:00 a.m. and 5:00 p.m. CT, Monday through Friday.

LEGAL RIGHTS: You are not waiving any of your legal rights by signing this consent form.

This form concerns two types of material that are helpful in research: (1) Blood, Tissue, and other bodily fluids and (2) Patient Information. Each is explained below, with space provided to mark your choice.

TISSUE AND BODILY FLUIDS: Investigators studying diseases can learn much about diseases from your tissue, blood and other bodily fluids, whether you have a disease or not. If tissue, blood, or other bodily fluids are taken for diagnostic tests and remain available after those tests are completed, we may wish to use those for future research. Reports about such research done with your sample(s) would *not* be given to you or your doctor, and these reports would *not* be put in your health records. In the future, people who do research with your sample(s) may need to know more information about your health that would be obtained from your medical record.

Sometimes tissue, blood, or other bodily fluids may be used for genetic research (about diseases that are passed on in families). Even if your sample(s) were used for this kind of research, the results would not be put in your health records.

Research with tissue, blood or other bodily fluids may result in the development of beneficial treatments, devices, new drugs, or patentable procedures, from which you will not receive any financial benefits or compensation.

CONSENT:
Tissue, blood, and other bodily fluids, if not disposed of, may be kept and used in research by UAB and others to learn about, prevent, treat, or cure cancer and other health problems and diseases. I agree to allow my extra tissue, blood, and other bodily fluids to be used for research.

YES □ _____ initials NO □ _____initials

I agree to have up to 20 milliliters (5 teaspoons) of blood not needed for diagnosis to be collected,

YES □ _____ initials NO □ _____initials

a urine sample,

YES □ _____ initials NO □ _____initials

and/or a saliva sample.

YES □ _____ initials NO □ _____initials

Medical researchers also can learn about various diseases from general information about groups of patients with the diseases as well as groups of matched individuals who do not have the diseases. This information would be gathered from patients' medical records, matched with tissues and held securely with access given only to approved researchers.

I agree to allow information from my medical record to be used in research to learn about the prevention, treatment, or cure of diseases and other health problems.

YES □ _____ initials NO □ _____initials

My information **can** be used in identifying genetic diseases that are at risk to my family members who might develop diseases similar to my disease.

YES □ _____ initials NO □ _____initials

SIGNATURES
Your signature below indicates that you give permission as noted above for your excess tissues, fluids, and/or medical information to be used in research. You will receive a copy of this informed consent.

_____ _____
Printed Name of Participant Date

_____ _____
Signature of Participant or Legally Authorized Representative Date

_____ _____
Signature of Principal Investigator or Person Obtaining Consent Date

_____ _____
Signature of Witness Date

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant name: _____ **UAB IRB Protocol Numbers:** F000629008, F990630015 X030820006, F940831016, X030820007

Research Protocol: Protocol for Obtaining Solid Tissues, Fluids, and Information for Research for the UAB Tissue Collection and Tumor Banking Facility Including the Breast, Ovarian, and Pancreatic SPORES, the Cooperative Human Tissues Network, the Cancer Center Tissue Core Facility, and the Genitourinary Research Center. **Principal Investigator:** William E. Grizzle, M.D., Ph.D. **Sponsor:** National Cancer Institute

What health information do the researchers want to use? All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, the UAB Health Services Foundation, The Children's Hospital of Alabama, Callahan Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the UAB Institutional Review Board and its staff, who are responsible for the protection of humans in research performed at UAB; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Our study protocol permits us to provide your remnant tissues with associated protected health care information to medical researchers; however, these are provided with no direct patient identifiers, and researchers cannot gain access to your identity. In addition, researchers agree to not attempt to discover your identity; thus, your identity is protected even though these researchers may not be required to follow Federal privacy laws. Your health information may be reviewed by employees of the sponsor of this study, the National Cancer Institute. Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws; however, all employees of other organizations that are not required to follow federal privacy laws who have access to patient information for this study will be required to sign a confidentiality agreement. Once your information is given to these other organizations, we cannot absolutely assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number provided above. Information on contacting the Director of the IRB is provided in the "Questions" paragraph of the Informed Consent document. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant:_____ Date:_____

or participants' legally authorized representative:_____ Date:_____

Printed Name of participant's representative:_____

Relationship to the participant:_____